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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/650,217	08/19/2003	John Graeme Houston	081421.000002	7117

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EXAMINER

AUGHENBAUGH, WALTER

ART UNIT	PAPER NUMBER
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1772

DATE MAILED: 03/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/650,217

Applicant(s)

HOUSTON ET AL.

Examiner

Walter B. Aughenbaugh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 August 2005 and 14 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 33-37 and 47-52 is/are pending in the application.
- 4a) Of the above claim(s) 50-52 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 33-37 and 47-49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>8/19/03</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I, claims 33-37 and 47-49 in the reply filed on August 1, 2005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains; or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claim 33 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification does not describe what is meant by the phrase "spiral-flow inducing properties", including which properties qualify as "spiral-flow inducing properties".

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 33 and 49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In regard to claim 33, the scope Applicant intends to delineate by the phrase "spiral-flow inducing properties" cannot be ascertained; therefore that which Applicant intends to recite in the phrase "spiral-flow inducing properties" cannot be ascertained.

In regard to claim 49, that which Applicant intends to recite in the phrase "is axially contractible on the support rod" cannot be ascertained: the recitation "the sleeve is axially contractible on the support rod" is contradictory to the structural relationship between the support rod and the sleeve that is recited in claim 49: if the sleeve is "mounted to the support rod" as recited, how would the sleeve be "axially contractible on the support rod"? Clarification is requested.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 33-37 and 47-49 are rejected under 35 U.S.C. 102(b) as being anticipated by Frassica.

In regard to claim 33, Frassica teaches an intravascular stent (col. 19, lines 19-41) having spiral flow inducing properties (item 301, Fig. 16, the stent has spiral flow inducing properties because urine would flow around the outside of the stent as guided by the spiral thread, item 303).

In regard to claim 34, Frassica teaches that the stent is an expansible mesh member (col. 5, lines 40-46) and that the mesh member has an internal spiral formation after expansion (coiled

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sidewall reinforcement member, item 310, Fig. 17, col. 19, lines 34-36). The recitation “is inserted by catheterization in collapsed form and which becomes expanded on release from the catheter is a method limitation which has not been given patentable weight since the method of forming the stent is not germane to the patentability of the stent itself.

In regard to claim 35, Frassica teaches that the mesh member comprises wire (spiral thread, item 303) extending helically around the periphery of the stent and that the internal spiral formation (coiled sidewall reinforcement member, item 310) comprises a helical vane member (coiled sidewall reinforcement member, item 310, is a helical vane member) attached to the wire, item 303 via the walls of the stent (Fig. 16 and 17).

In regard to claim 36, Frassica teaches that the stent has a helical formation (coiled sidewall reinforcement member, item 310, Fig. 17, col. 19, lines 34-36) thereon which would induce spiral flow and is adjustable (col. 19, lines 36-41).

In regard to claim 37, Frassica teaches that the stent further comprises a rigid support (the wall of the stent (Fig. 16 and 17) and a spiral flow inducer vane (thread, item 303) mounted to and extending from the rigid support and that the vane has an adjustable helix angle (col. 19, lines 21-26).

In regard to claim 47, Frassica teaches an intravascular stent (col. 19, lines 19-41) comprising an expansible tubular mesh member (col. 5, lines 40-46) having a vane (coiled sidewall reinforcement member, item 310) that is stationarily attached to an interior thereof. The mesh member is adapted to be inserted into and retained within a vein since it is a stent: it has been held that the recitation that an element is “adapted to” perform a function is not a positive limitation but only requires the ability to so perform. *In re Hutchinson*, 69 USPQ 138. The spiral

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(which extends helically) of the coiled sidewall reinforcement member, item 310, would necessarily induce spiral flow of blood.

In regard to claim 48, Frassica teaches that the stent is a tubular metallic mesh device (col. 5, lines 40-42), and metallic mesh necessarily comprises a plurality of wires that extend helically and cross each other to form junctions.

In regard to claim 49, Frassica teaches that the stent comprises a rigid support rod (external thread, item 303), a flexible sleeve (tube, item 302) mounted to the support rod and a flexible helical vane (coiled sidewall reinforcement member, item 310) mounted to the sleeve (col. 19, lines 19-36 and Fig. 16 and 17). The sleeve of Frassica is axially contractible on the support rod since Frassica teaches that it is expandable by design (col. 5, lines 40-44). Axially contracting the stent necessarily varies the angle of the vane (coiled sidewall reinforcement member, Fig. 16 and 17).

Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Walter B. Aughenbaugh whose telephone number is 571-272-1488. While the examiner sets his work schedule under the Increased Flexitime Policy, he can normally be reached on Monday-Friday from 8:45am to 5:15pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon, can be reached on 571-272-1498. The fax phone number for the organization where this application or proceeding is assigned is to 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications

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may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Walter B. Aughenbaugh

03/20/06

WBA



HAROLD PYON
SUPERVISORY PATENT EXAMINER

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3/20/06